UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/835,482	4-8-1997	RUBIN, ALAN	—

EXAMINER
H. SHEIKH

ART UNIT	PAPER NUMBER
1615	38

DATE MAILED:

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) HUMERA N. SHEIKH (3) Dr. ALAN RUBIN

(2) KISHORE GOLLAMUDI, PH.D. (4)

Date of Interview 24 JULY 2003

Type: ☐ Telephonic ☐ Televideo Conference ☒ Personal (copy is given to ☒ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: 1, 11, 12, 17~~-20~~, 21-23 (ON RECORD)

Identification of prior art discussed: ON RECORD (CONTE + DEMSKI)

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: Dr Rubin discussed instant ~~claim~~ two layered tablet and the differences between instant product Vs Demski's and Conte's Conte's formulation is a 3 layered formulation. Since the application went to the board (& affirmed) the examiner will review applicant's additional arguments & and any additional ~~re~~ amendments to the claims and determine the patentability. If ~~any~~ any changes are deemed necessary to make the claims allowable, ~~the examiner will call the applicant, if necessary~~.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has are ready been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

Examiner Note: You must sign this form unless it is an attachment to another form.

G S Kishore

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

FORM PTOL-413 (REV. 2-98)

Manual of Patent Examining Procedure, Section 713.04 Substance of Interview must Be Made of Record

Except as otherwise provided, a complete written statement as to the substance of any face-to-face or telephone interview with regard to an application must be made of record in the application, whether or not an agreement with the examiner was reached at the interview.

§1.133 Interviews

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(b) In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111 and 1.135. (35 U.S.C. 132)

§ 1.2. Business to be transacted in writing. All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete a two-sheet carbon interleaf Interview Summary Form for each interview held after January 1, 1978 where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks in neat handwritten form using a ball point pen. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, pointing out typographical errors or unreadable script in Office actions or the like, or resulting in an examiner's amendment that fully sets forth the agreement are excluded from the interview recordation procedures below.

The Interview Summary Form shall be given an appropriate paper number, placed in the right hand portion of the file, and listed on the "Contents" list on the file wrapper. In a personal interview, the duplicate copy of the Form is removed and given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephonic interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication.

The Form provides for recordation of the following information:

- Application Number of the application
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (personal or telephonic)
- Name of participant(s)) (applicant, attorney or agent, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the claims discussed
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). (Agreements as to allowability are tentative and do not restrict further action by the examiner to the contrary.)
- The signature of the examiner who conducted the interview
- Names of other Patent and Trademark Office personnel present.

The Form also contains a statement reminding the applicant of his responsibility to record the substance of the interview.

It is desireable that the examiner orally remind the applicant of his obligation to record the substance of the interview in each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check a box at the bottom of the Form informing the applicant that he need not supplement the Form by submitting a separate record of the substance of the interview.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview:

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner. The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he feels were or might be persuasive to the examiner,
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete or accurate, the examiner will give the applicant one month from the date of the notifying letter to complete the reply and thereby avoid abandonment of the application (37 CFR 1.135(c)).

Examiner to Check for Accuracy

Applicant's summary of what took place at the interview should be carefully checked to determine the accuracy of any argument or statement attributed to the examiner during the interview. If there is an inaccuracy and it bears directly on the question of patentability, it should be pointed out in the next Office letter. If the claims are allowable for other reasons of record, the examiner should send a letter setting forth his or her version of the statement attributed to him. If the record is complete and accurate, the examiner should place the indication "Interview record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Draft Claims Revised Following Interview at USPTO on 7/24/03

21. (New) A method for treating Parkinson's disease in a patient having need of such treatment comprising orally administering at least one bilayer tablet to said patient, said tablet having a sustained release core layer consisting essentially of 25-75 mg carbidopa, 100-400 mg levodopa, methocel, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate, and an immediate release outer layer over said sustained release core layer, said immediate release layer consisting essentially of 10-25 mg carbidopa, 50-200 mg levodopa, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate.

22. (New) A method according to claim 21, wherein said immediate release outer layer contains 25 mg carbidopa, 100 mg levodopa, 224 mg microcrystalline cellulose, 15 mg croscarmellose sodium, 3.0 mg silicon dioxide and 3.0 mg magnesium stearate, and said sustained release core layer contains 50 mg carbidopa, 200 mg levodopa, 80 mg methocel, 61 mg microcrystalline cellulose, 15 mg croscarmellose sodium, 2.0 mg silicon dioxide and 2.0 mg magnesium stearate, the mg being mg/tablet.

23. (New) A method according to claim 21, wherein said immediate release outer layer contains 12.5 mg carbidopa, 50 mg levodopa, 123.5 mg microcrystalline cellulose, 2.0 mg silicon dioxide and 10 mg magnesium stearate, and said sustained release core contains 37.5 mg carbidopa, 150 mg levodopa, 80 mg methocel, 53.5 mg microcrystalline cellulose, 2.0 mg silicon dioxide and 2.0 mg magnesium stearate, the mg being mg/tablet.

Allan Rubin

7/28/03

levodopa to dopamine (US Pat No 5, 738, 874, col. 2, lines 42-56) and (2) the use of carbidopa to inhibit peripheral decarboxylation of levodopa (US Pat No 5, 738, 874, col 2, lines 57-65) to support the need for sequential release of carbidopa-levodopa (Goodman and Gilman's The Pharmacological Basis of Therapeutics, Pergamon Press, New York, NY, 8th ED. pp 466-472, 1990). Therefore, neither conte nor Dempski have recognized the problem solved by this invention, ie, the rationale for immediate and long lasting therapeutic action of carbidopa-levodopa in Parkinson's disease. Recognition of an unreconized problem militates for patentability.

If Conte's release profile and basis for utility are not novel, then the essence of his invention may relate to his formulations per se. In this regard, the formulations of the present invention differ significantly from those of Conte. For example, Conte claims a 3-layer tablet consisting of a first layer containing immediate or controlled release drugs, a second layer containing one or more drugs either equal to or different from the first layer and a third, rate-controlling barrier layer containing drug, if necessary.

The present invention teaches a bilayer or multilayer tablet as well as a capsule dosage form containing pellets. The bilayer and pellet (capsule) dosage forms are not included in Conte's patent; moreover, they comprise a sustained release core of carbidopa-levodopa overcoated only with an immediate release layer of carbidopa-levodopa. In addition, the multilayer tablets of the present invention contain an excipient layer which, unlike Conte's third barrier layer, may be drug-free and does not necessarily contain rate-controlling polymers. In view of the above argument, applicant submits that this application is in condition for allowance. Such action is respectfully requested.

Respectfully submitted

Alan A. Rubin
Applicant (Tel. 302, 478-0838)

Certificate of Mailing-37CFR1.8(a): I hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to: Ass't Commissioner for Patents, Washington, DC 20231 on May 14, 1999, adequate postage applied.

Alan A. Rubin